Section 256a of this title, referred to in subsec. (e), was repealed by Pub. L. 104-299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

AMENDMENTS

2003—Subsec. (e). Pub. L. 108-163 substituted "254b" for "254c, 254b(h)" before ", 256a".

2002—Subsec. (e). Pub. L. 107–251 substituted "254b(h)" for "256".

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, §304, which enacted this section.

Subsec. (o)(2). Pub. L. 103–183, §402(a), substituted "subsection (q)" for "subsection (s)".

Subsec. (q). Pub. L. 103-183, §402(b)(1), substituted "through 1998" for "and 1995".

Subsec. (r)(2). Pub. L. 103–183, \$402(b)(2), substituted "1998" for "1995".

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

§ 247c-2. Data collection regarding programs under subchapter XXIV

For the purpose of collecting and providing data for program planning and evaluation activities under subchapter XXIV, there are authorized to be appropriated to the Secretary (acting through the Director of the Centers for Disease Control and Prevention) such sums as may be necessary for each of the fiscal years 2001 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for such purpose.

(July 1, 1944, ch. 373, title III, §318B, as added Pub. L. 106-345, title IV, §412, Oct. 20, 2000, 114 Stat. 1350.)

§ 247d. Public health emergencies

(a) Emergencies

If the Secretary determines, after consultation with such public health officials as may be necessary, that—

- (1) a disease or disorder presents a public health emergency; or
- (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,

the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing

awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determina-

(b) Public Health Emergency Fund

(1) In general

There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) Uses

The Secretary may use amounts in the Fund established under paragraph (1), to—

(A) facilitate coordination between and among Federal, State, local, Tribal, and territorial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency referred to in paragraph (1) (including communication of such entities with relevant international entities, as applicable);

(B) make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to a public health emergency or potential public health emergency, including further supporting programs under section 247d-3a, 247d-3b, or 247d-3c of this title;

(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 247d-6b of this title), qualified countermeasures (as defined in section 247d-6a of this title), or qualified pandemic or epidemic products (as defined in section 247d-6d of this title), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect,

and analyze information regarding such public health emergency or potential public health emergency, including the systems under section 247d-4 of this title;

- (E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel under section 300hh–11 of this title and the Medical Reserve Corps under section 300hh–15 of this title; and
- (F) carry out other activities, as the Secretary determines applicable and appropriate.

(3) Report

Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing—

- (A) the expenditures made from the Public Health Emergency Fund in such fiscal year; and
- (B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

(4) Review

Not later than 2 years after June 24, 2019, the Secretary, in coordination with the Assistant Secretary for Preparedness and Response, shall conduct a review of the Fund under this section and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

(5) GAO report

Not later than 4 years after June 24, 2019, the Comptroller General of the United States shall— $\,$

- (A) conduct a review of the Fund under this section, including its uses and the resources available in the Fund; and
- (B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review, including recommendations related to such review, as applicable.

(c) Supplement not supplant

Funds appropriated under this section shall be used to rapidly respond to public health emergencies or potential public health emergencies and supplement and not supplant other Federal, State, and local public funds provided for activities under this chapter or funds otherwise provided for emergency response.

(d) Data submittal and reporting deadlines

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

(e) Temporary reassignment of State and local personnel during a public health emergency (1) Emergency reassignment of federally fund-

Notwithstanding any other provision of law, and subject to paragraph (2), upon request by the Governor of a State or a tribal organization or such Governor or tribal organization's designee, the Secretary may authorize the requesting State or Indian tribe to temporarily reassign, for purposes of immediately addressing a public health emergency in the State or Indian tribe, State and local public health department or agency personnel funded in whole or in part through programs authorized under this chapter, as appropriate.

(2) Activation of emergency reassignment

(A) Public health emergency

ed personnel

The Secretary may authorize a temporary reassignment of personnel under paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) Contents of request

To seek authority for a temporary reassignment of personnel under paragraph (1), the Governor of a State or a tribal organization shall submit to the Secretary a request for such reassignment flexibility and shall include in the request each of the following:

- (i) An assurance that the public health emergency in the geographic area of the requesting State or Indian tribe cannot be adequately and appropriately addressed by the public health workforce otherwise available.
- (ii) An assurance that the public health emergency would be addressed more efficiently and effectively through the requested temporary reassignment of State and local personnel described in paragraph (1).
- (iii) An assurance that the requested temporary reassignment of personnel is consistent with any applicable All-Hazards Public Health Emergency Preparedness and Response Plan under section 247d–3a of this title.
 - (iv) An identification of-
 - (I) each Federal program from which personnel would be temporarily reassigned pursuant to the requested authority; and
 - (II) the number of personnel who would be so reassigned from each such program.

(v) Such other information and assurances upon which the Secretary and Governor of a State or tribal organization agree.

(C) Consideration

In reviewing a request for temporary reassignment under paragraph (1), the Secretary shall consider the degree to which the program or programs funded in whole or in part by programs authorized under this chapter would be adversely affected by the reassignment.

(D) Termination and extension

(i) Termination

A State or Indian tribe's temporary reassignment of personnel under paragraph (1) shall terminate upon the earlier of the following:

- (I) The Secretary's determination that the public health emergency no longer exists.
- (II) Subject to clause (ii), the expiration of the 30-day period following the date on which the Secretary approved the State or Indian tribe's request for such reassignment flexibility.

(ii) Extension of reassignment flexibility

The Secretary may extend reassignment flexibility of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists as of such date, but only if—

- (I) the State or Indian tribe that submitted the initial request for a temporary reassignment of personnel submits a request for an extension of such temporary reassignment; and
- (II) the request for an extension contains the same information and assurances necessary for the approval of an initial request for such temporary reassignment pursuant to subparagraph (B).

(3) Voluntary nature of temporary reassignment of State and local personnel

(A) In general

Unless otherwise provided under the law or regulation of the State or Indian tribe that receives authorization for temporary reassignment of personnel under paragraph (1), personnel eligible for reassignment pursuant to such authorization—

- (i) shall have the opportunity to volunteer for temporary reassignment; and
- (ii) shall not be required to agree to a temporary reassignment.

(B) Prohibition on conditioning Federal awards

The Secretary may not condition the award of a grant, contract, or cooperative agreement under this chapter on the requirement that a State or Indian tribe require that personnel eligible for reassignment pursuant to an authorization under paragraph (1) agree to such reassignment.

(4) Notice to Congress

The Secretary shall give notice to the Congress in conjunction with the approval under this subsection of—

- (A) any initial request for temporary reassignment of personnel; and
- (B) any request for an extension of such temporary reassignment.

(5) Guidance

The Secretary shall—

- (A) not later than 6 months after March 13, 2013, issue proposed guidance on the temporary reassignment of personnel under this subsection; and
- (B) after providing notice and a 60-day period for public comment, finalize such guidance.

(6) Report to Congress

Not later than 4 years after March 13, 2013, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of the Congress a report, on temporary reassignment under this subsection, including—

- (A) a description of how, and under what circumstances, such temporary reassignment has been used by States and Indian tribes:
- (B) an analysis of how such temporary reassignment has assisted States and Indian tribes in responding to public health emergencies:
- (C) an evaluation of how such temporary reassignment has improved operational efficiencies in responding to public health emergencies:
- (D) an analysis of the extent to which, if any, Federal programs from which personnel have been temporarily reassigned have been adversely affected by the reassignment; and
- (E) recommendations on how medical surge capacity could be improved in responding to public health emergencies and the impact of the reassignment flexibility under this section on such surge capacity.

(7) Definitions

In this subsection—

- (A) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 5304 of title 25; and
- (B) the term "State" includes, in addition to the entities listed in the definition of such term in section 201 of this title, the Freely Associated States.

(8) Sunset

This subsection shall terminate on September 30, 2023.

(f) Determination with respect to Paperwork Reduction Act waiver during a public health emergency

(1) Determination

If the Secretary determines, after consultation with such public health officials as may be necessary, that—

- (A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or
- (ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44 (commonly referred to as the Paperwork Reduction Act).

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

(2) Transparency

If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

(3) Effectiveness of waiver

Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

(4) Termination of waiver

Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

(5) Limitations

(A) Period of waiver

The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

(B) Subsequent compliance

An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44 and the Secretary shall en-

sure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.

(July 1, 1944, ch. 373, title III, §319, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2315; amended Pub. L. 107–188, title I, §§141, 144(a), 158, June 12, 2002, 116 Stat. 626, 630, 633; Pub. L. 113–5, title II, §201, Mar. 13, 2013, 127 Stat. 170; Pub. L. 114–255, div. A, title III, §3087, Dec. 13, 2016, 130 Stat. 1147; Pub. L. 116–22, title II, §206, title VII, §701(c), June 24, 2019, 133 Stat. 925, 961.)

PRIOR PROVISIONS

A prior section 247d, act July 1, 1944, ch. 373, title III, $\S 319$, as added Pub. L. 98–49, July 13, 1983, 97 Stat. 245; amended Pub. L. 100–607, title II, $\S 256(a)$, Nov. 4, 1988, 102 Stat. 3110; Pub. L. 102–321, title I, $\S 163(b)(2)$, July 10, 1992, 106 Stat. 376; Pub. L. 102–531, title III, $\S 312(d)(2)$, Oct. 27, 1992, 106 Stat. 3504, authorized the Secretary to take appropriate action relating to public health emergencies, prior to repeal by Pub. L. 106–505, title I, $\S 102$, Nov. 13, 2000, 114 Stat. 2315.

Another prior section 247d, act July 1, 1944, ch. 373, title III, §319, formerly §310, as added Sept. 25, 1962, Pub. L. 87-692, 76 Stat. 592, and amended and renumbered, which related to migrant health centers, was renumbered section 329 of act July 1, 1944, by Pub. L. 95-626, title I, §102(a), Nov. 10, 1978, 92 Stat. 3551, and transferred to section 254b of this title, prior to being omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104-299, §2

AMENDMENTS

2019—Subsec. (b)(1). Pub. L. 116–22, §206(1)(A), substituted "under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities." for "under such subsection."

Subsec. (b)(2), (3). Pub. L. 116–22, §206(1)(B), (C), added par. (2) and redesignated former par. (2) as (3).

Subsec. (b)(4), (5). Pub. L. 116–22, §206(1)(D), added pars. (4) and (5).

Subsec. (c). Pub. L. 116–22, \$206(2), inserted "rapidly respond to public health emergencies or potential public health emergencies and" after "used to" and substituted "activities under this chapter or funds otherwise provided for emergency response." for "activities under this section."

Subsec. (e)(8). Pub. L. 116-22, §701(c), substituted "2023" for "2018".

2016—Subsec. (f). Pub. L. 114–255 added subsec. (f).

2013—Subsec. (e). Pub. L. 113-5 added subsec. (e). 2002—Subsec. (a). Pub. L. 107-188, §158, substituted 'grants, providing awards for expenses, and' for 'grants and' in concluding provisions.

Pub. L. 107–188, §144(a), inserted at end of concluding provisions "Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination."

Subsec. (d). Pub. L. 107-188, §141, added subsec. (d).

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–188, title I, §144(b), June 12, 2002, 116 Stat. 630, provided that: "The amendment made by subsection (a) [amending this section] applies to any public health emergency under section 319(a) of the Public Health Service Act [42 U.S.C. 247d(a)], including any such emergency that was in effect as of the day before the date of the enactment of this Act [June 12, 2002]. In the case of such an emergency that was in effect as of such day, the 90-day period described in such section with respect to the termination of the emergency is deemed to begin on such date of enactment."

IMPORTANCE OF THE BLOOD SUPPLY

Pub. L. 116–136, div. A, title III, §3226, Mar. 27, 2020, 134 Stat. 383, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall carry out a national campaign to improve awareness of, and support outreach to the public and health care providers about the importance and safety of blood donation and the need for donations for the blood supply during the public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d) with respect to COVID-19.

"(b) AWARENESS CAMPAIGN.—In carrying out subsection (a), the Secretary may enter into contracts with one or more public or private nonprofit entities, to establish a national blood donation awareness campaign that may include television, radio, internet, and newspaper public service announcements, and other activities to provide for public and professional awareness and education.

"(c) Consultation.—In carrying out subsection (a), the Secretary shall consult with the Commissioner of Food and Drugs, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the heads of other relevant Federal agencies, and relevant accrediting bodies and representative organizations.

G(d) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act [Mar. 27, 2020], the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that shall include—

"(1) a description of the activities carried out under subsection (a);

"(2) a description of trends in blood supply donations; and

"(3) an evaluation of the impact of the public awareness campaign, including any geographic or population variations."

REPORTING BY LABORATORIES OF RESULTS OF TESTS TO DETECT SARS-COV-2 OR TO DIAGNOSE COVID-19

Pub. L. 116–136, div. B, title VIII, \$18115(a)-(c), Mar. 27, 2020, 134 Stat. 574, provided that:

"(a) IN GENERAL.—Every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration with respect to COVID-19 or any extension of such declaration.

"(b) LABORATORIES COVERED.—The Secretary may prescribe which laboratories must submit reports pursuant to this section.

"(c) IMPLEMENTATION.—The Secretary may make prescriptions under this section by regulation, including by interim final rule, or by guidance, and may issue such regulations or guidance without regard to the procedures otherwise required by section 553 of title 5, United States Code."

§ 247d-1. Vaccine tracking and distribution

(a) Tracking

The Secretary, together with relevant manufacturers, wholesalers, and distributors as may agree to cooperate, may track the initial distribution of federally purchased influenza vaccine in an influenza pandemic. Such tracking information shall be used to inform Federal, State, local, and tribal decision makers during an influenza pandemic.

(b) Distribution

The Secretary shall promote communication between State, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate, regarding the effective distribution of seasonal influenza vaccine. Such communication shall include estimates of high priority populations, as determined by the Secretary, in State, local, and tribal jurisdictions in order to inform Federal, State, local, and tribal decision makers during vaccine shortages and supply disruptions.

(c) Confidentiality

The information submitted to the Secretary or its contractors, if any, under this section or under any other section of this chapter related to vaccine distribution information shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18 relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage.

(d) Guidelines

The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to provide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines for subsections (a) and (b).